

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS U.S. LLC et al.,

Plaintiffs,

V.

MYLAN GMBH et al.,

Defendants.

Civil Action No. 17-9105 (SRC)

OPINION & ORDER

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for summary judgment of invalidity by Defendants Mylan GmbH, Biocon Research Ltd., Biocon S.A., and Biocon Sdn. Bhd. (collectively, “Mylan”). Plaintiffs Sanofi Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie (“Sanofi”) have opposed the motion. For the reasons that follow, the motion will be denied.

Mylan moves for summary judgment of invalidity of U.S. Patent Nos. 7,476,652 and 7,713,930 (together, the “formulation patents.”) In short, Mylan argues that collateral estoppel bars Sanofi from relitigating invalidity due to obviousness as to the formulation patents. There is no dispute that, previously, Defendants filed petitions for *Inter Partes* Review of these patents and that, in December of 2018, the PTAB issued Final Written Decisions which found that both formulation patents were invalid due to obviousness. Appeals of the PTAB decisions are pending before the Federal Circuit.

The Supreme Court has stated the following standard for finding issue preclusion: “the

general rule is that when an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.”

B&B Hardware, Inc. v. Hargis Indus., 135 S. Ct. 1293, 1303 (2015) (quoting Restatement (Second) of Judgments §27, p. 250 (1980)).

Sanofi, in opposition, argues that issue preclusion or collateral estoppel cannot apply where, as here, the first and second proceedings apply different burdens of proof. Sanofi points out that the presumption of patent validity did not apply before the PTAB, and that, in that proceeding, the Petitioner’s burden was to demonstrate obviousness by a preponderance of the evidence. In the instant proceeding, Mylan must prove invalidity by clear and convincing evidence. Microsoft Corp. v. i4i Ltd. P’ship, 564 U.S. 91, 97 (2011).

Mylan, in reply, does not dispute Sanofi’s assertions about the differing burdens of proof but, rather, contends that the Supreme Court rejected such distinctions in B&B Hardware. The cited portion of B&B Hardware does not, however, support Mylan’s position, since it holds merely that the procedural differences between the PTAB and district courts do not bar issue preclusion. 135 S. Ct. at 1309. Sanofi’s argument here does not rely on procedural differences but on differences in the legal standard, and the B&B Hardware decision states clearly: “[I]ssues are not identical if the second action involves application of a different legal standard, even though the factual setting of both suits may be the same.” 135 S. Ct. 1293, 1306 (quoting 18 C. Wright, A. Miller, & E. Cooper, Federal Practice & Procedure § 4417, p. 449 (2d ed. 2002)). In the instant case, the second action in this Court involves application of a different legal standard than the PTAB applied.

Mylan has failed to demonstrate that it is entitled to judgment as a matter of law, pursuant to Federal Rule of Civil Procedure 56. The motion for summary judgment will be denied.

For these reasons,

IT IS on this 2nd day of October, 2019

ORDERED that Defendants' motion for summary judgment of invalidity (Docket Entry No. 353) is **DENIED**.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.